

K061180

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document is accurate and complete to the best of KSEA's knowledge.

Applicant: Karl Storz Endoscopy - America, Inc.
600 Corporate Pointe Drive
Culver City, CA 90230
(310) 338-8100

JUL 27 2006

Contact: James A. Lee, Ph.D.
Senior Regulatory Affairs Specialist

Device Identification: Common Name:
Tissue Morcellator

Trade Name: (optional)
KSEA ROTOCUT G1 Electromechanical Morcellator

Indication: The ROTOCUT G1 Electromechanical Morcellator in conjunction with the UNIDRIVE GYN Control unit is a motorized unit for morcellating and extracting tissue during laparoscopic procedures in general surgery, gynecology including the removal of myomas and hysterectomy, and urology including nephrectomy.

Device Description: The KSEA ROTOCUT G1 Electromechanical Morcellator in conjunction with the UNIDRIVE GYN control unit is a motorized, reusable surgical device system, intended for the morcellation and extracting tissue during laparoscopic procedures in general surgery, gynecology, and urology by qualified surgeons.

Substantial Equivalence: The KSEA ROTOCUT G1 Electromechanical Morcellator is substantially equivalent to the predicate devices since the basic features, design and intended uses are similar. The minor differences in design and dimensions between the KSEA ROTOCUT G1 Electromechanical Morcellator and the predicate devices raise no new issues of safety and effectiveness, as these design differences have no effect on the performance, function or intended use of these devices.

Signed: 

James A. Lee, Ph.D.
Senior Regulatory Affairs Specialist



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 27 2006

Karl Storz Endoscopy
% James A. Lee, Ph.D.
Senior Regulatory Affairs Specialist
600 Corporate Pointe, 5th Floor
Culver City, California 90230-7600

Re: K061180

Trade/Device Name: KSEA ROTOCUT G1 Electromechanical Morcellator and
Accessories
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ, HET
Dated: June 29 2006
Received: June 30, 2006

Dear Dr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

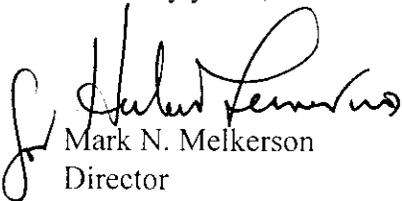
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

Page 2 – James A. Lee, Ph.D.

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is written in a cursive style with a large initial "M".

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K061180

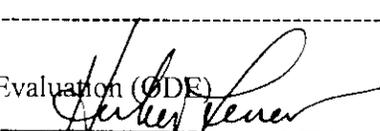
Device Name: KSEA ROTOCUT G1 Electromechanical Morcellator and Accessories

Indication for Use: The ROTOCUT G1 Electromechanical Morcellator in conjunction with the UNIDRIVE GYN Control unit is a motorized unit for morcellating and extracting tissue during laparoscopic procedures in general surgery, gynecology including the removal of myomas and hysterectomy, and urology including nephrectomy.

Prescription Use: X OR Over-The-Counter Use:
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

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